Al Labuz (Honeywell) has asked for a response to their OLSQV position contained in my 11/28 email (12/7 meeting agenda) to your attention. Listed below is a proposed position that I would like your comments on, before I pass it on to Honeywell in writing or verbally. The technical basis for our position originated with Tim Sinnott (DEC, Division of Fish, Wildlife & Marine Resources) . Please provide me with any comments you may have, on the text listed below, asap but no later than c.o.b. Friday, January 5th.
Thank you,
Tim

The Department objects to the use of the Adverse Effects Threshold (AET) methodology as the sole basis for setting OLSQVs because it minimizes, actually eliminates, type 1 errors (false positives) at the expense of type 2 errors (false negatives). Therefore, the use of AETs, as a cleanup criteria, will leave contaminated sites that show biological effects unmitigated. For example, using the 1992 chironomid growth test results for mercury, Honeywell/Exponent determined the AET to be 5.5 mg/kg Hg. The NOEL was 1.6 mg/kg Hg. There were 29 sample sites, 13 of which showed effects (representing 17 concentrations, 9 of which showed effects) that were <5.5 and >1.6 mg/kg Hg. Exponent contends that toxicity at sites with contaminant concentrations below AET thresholds are probably attributable to some other cause besides the particular contaminant of interest. That cannot be taken for granted. AETs would be acceptable if a thorough TIE [Tim - please define TIE.] evaluation was conducted at each site at which the concentration of the contaminant of interest (COI) was below the AET and biological effects were detected.

The Department also objects to the designation of "primary" OLSQVs, and "secondary" OLSQVs. There is no basis for such a designation. The OLSQVs should be based on the lowest COI concentration that shows a statistically significant biological effect, regardless of which of the five tests showed the effect (Hyalella acute, Hyalella chronic, chironomid acute, chironomid chronic, benthic community analysis).

There are a number of methods for deriving empirical site specific sediment criteria. Most of which require the selection of an arbitrary effects level. The Theresa Michelson's error analysis based method involves the use of selecting an acceptable error level that is not arbitrary. Therefore, the Department proposes an approach for setting OLSQVs that is loosely based on Theresa Michelson's error-analysis based approach. This approach is to simply calculate the type 1 and type 2 error at every sample concentration between the AET and the NOEL, and select for the OLSQV the COI where they type 1 and type 2 errors are minimized relative to each other. For the 1992 Onondaga Lake chironomid growth data for mercury, this concentration would be 2.8 mg/kg Hg, corresponding to site S40. The type 1 and type 2 error rates at this concentration are 0.24 and 0.23 respectively.

Consultant in Oregon - done this for clients in western part of country. Michelson uses arbitrary % figures

Since that time, EPA OERR has developed a draft probabilistic risk assessment guidance that recently completed peer review. The draft document is available on http://www.epa.gov/oerrpage/superfund/programs/risk/rags3adt/index.htm. Please note that this document is draft, and will be revised over the next several months to respond to questions raised by the external peer-reviewers. I do not anticipate that the requirement for submitting a workplan will change in this time frame. As you might imagine, there are a number of issues regarding the selection of input distributions and datasets that need to be resolved before performing the probabilistic risk assessment. Also note, that there is a tiered approach outlined in the Superfund guidance to address when it is appropriate to develop a Monte Carlo analysis. Depending on the nature of the contamination, the point estimate of risk, and the available data it may not be appropriate to conduct a Monte Carlo at all sites. The only site where a Monte Carlo was developed in the region, sofar, is the Hudson and essentially the results of the Monte Carlo supported those from the point estimate.

Please let me know if I can provide any additional information.

Marian
Robert Nunes

Robert Nunes
01/11/01 03:46 PM

To: Marian Olsen/R2/USEPA/US@EPA, Michael Sivak/R2/USEPA/US@EPA
cc:
Subject: Monte Carlo Guidance

Hi Marian and Mike - Gina suggested that I ask either of you for a copy of the current Monte Carlo guidance to see what is required for its preparation. Honeywell has provided a proposal for food web modelling for the Onondaga Lake site BERA which seems to be based on a Monte Carlo analysis that has yet to be prepared. Gina says EPA guidance indicates that a detailed workplan be prepared and reviewed before a Monte Carlo analysis be performed. Please let me know if you have something electronically or a hard copy that I could come down and pick up or photocopy. Thanks.

Bob
7-4254

Mindy Pensak
03/02/01 12:24 PM

To: Robert Nunes/R2/USEPA/US@EPA
cc:
Subject: Re: PRA question

Sounds like a reasonable course of action - also would want TAMs to check out all their assumptions/parameters that they will be inputting into the model. The value of the model will only be as strong as the data which go into it. I'll forward your question regarding peer review to someone in HQ - this is still a relatively new field for the agency, so I'm not sure if any PRAs have even gotten that far. Tuesday is fine for a call - just let me know what time. I may be reached at 908-232-3662 on that day.

Robert Nunes

Robert Nunes
03/02/01 11:07 AM

To: Mindy Pensak/R2/USEPA/US@EPA
cc:
Subject: Re: PRA question

Hi Mindy - Thanks for your follow-up. I think the call will be on Tues. but we haven't heard back from Honeywell yet. Prior to receiving a work plan we would like to request that Honeywell submit a justification for conducting the PRA. We believe this is consistent with the draft guidance which recommends that the decision to perform the PRA be made after determining that available info to support a PRA exists and that the PRA will enhance decision making at the site. Once we received and conceptually approved the decision to perform the PRA, then Honeywell could submit a Work Plan. Does this sound like an appropriate course of action? Also, assuming we go down this road and Honeywell develops a PRA, we are thinking that it may be something that we want to undergo peer review. Do you know if EPA has ever requested peer review for a PRP developed work product?

Bob
Mindy Pensak

Mindy Pensak
03/02/01 07:23 AM

To: Robert Nunes/R2/USEPA/US@EPA
cc:
Subject: PRA question

The person I contacted in Region 10 regarding PRAs indicated that some PRAs may have been accepted without approved workplans, but to do so is asking for problems. A workplan will allow the reviewer to make sure that the effort of the PRA will be worthwhile, a sensitivity analysis will be conducted, and that adequate information will be presented to review it. This I believe is in line with our thoughts on other efforts as well and is why we generally require workplans. Please let me know when the call will be scheduled for next week.

Thanks

Marian Olsen
01/24/01 04:42 PM

To: Robert Nunes/R2/USEPA/US@EPA
cc: Michael Sivak/R2/USEPA/US@EPA
Subject: Re: Monte Carlo Analysis

Hi Bob,

The site is in Region V and I'll send you the name of the RPM under another email. This happened a few weeks ago.

At the Hudson River Site we conducted a Monte Carlo Analysis for human health and a principle components analysis for the ecological risk assessment. I believe the principal components analysis is a more sophisticated statistical analysis but I'm not sure if it is classified as a Monte Carlo Analysis. Essentially, we went out to the public with the Scope of Work for the project, we spent significant resources on obtaining the datasets for the analysis and fitting the distributions, and then there was significant amounts of time associated with the development (computer models), writing the risk assessment, reviewing it, and revising it. I'm not sure about the exact costs of the analysis, but it required senior scientists from the contractor (i.e., specialized statistical support, risk assessors, and exposure assessors) and significant computer time to perform the runs. We also had several people in ORD and the regions involved in reviewing the document to assure that it met all criteria. Also, please note, that the contractor was EPAs. I would say the the development of the risk assessment took about 9 months to complete. You may want to contact Alison Hess for additional information.

Please let me know if I can provide any additional information.

Marian

Robert Nunes

Robert Nunes
01/24/01 02:52 PM

To: Marian Olsen/R2/USEPA/US@EPA
cc:
Subject: Monte Carlo Analysis

Hi Marian - We are still wrestling with this issue - specifically how to respond to a Honeywell foodweb modelling submittal that includes developing probabilistic risk assessment data. We have the following questions on this.

1. You indicated that a Monte Carlo Analysis was rejected in another Region because a Work Plan had not been provided. What region was that and when did this occur?

2. Looking at the guidance, it seems that conducting a MCA can require a great deal of resources and take an inordinate amount of time to complete. Is there an estimate you can give as to how long it might take? How long did it take to complete for the Hudson River site? And at the Hudson River site, was it done for Eco or HH or both?

Thank you for your help.

Mindy Pensak
03/02/01 07:23 AM

To: Robert Nunes/R2/USEPA/US@EPA
cc:
Subject: PRA question

The person I contacted in Region 10 regarding PRAs indicated that some PRAs may have been accepted without approved workplans, but to do so is asking for problems. A workplan will allow the reviewer to make sure that the effort of the PRA will be worthwhile, a sensitivity analysis will be conducted, and that adequate information will be presented to review it. This I believe is in line with our thoughts on other efforts as well and is why we generally require workplans. Please let me know when the call will be scheduled for next week.

Thanks

Marian Olsen

01/11/01 04:01 PM

To: Robert Nunes/R2/USEPA/US@EPA
cc: Michael Sivak/R2/USEPA/US@EPA
Subject: Re: Monte Carlo Guidance

Hi Bob,

In 1997, the Agency released a policy on probabilistic risk analysis along with general guidelines on what to look for in a probabilistic (i.e., Monte Carlo Analysis). This document is available on www.epa/gov/ncea under the section guidance and publications.

Since that time, EPA OERR has developed a draft probabilistic risk assessment guidance that recently completed peer review. The draft document is available on http://www.epa.gov/oerrpage/superfund/programs/risk/rags3adt/index.htm. Please note that this document is draft, and will be revised over the next several months to respond to questions raised by the external peer-reviewers. I do not anticipate that the requirement for submitting a workplan will change in this time frame. As you might imagine, there are a number of issues regarding the selection of input distributions and datasets that need to be resolved before performing the probabilistic risk assessment. Also note, that there is a tiered approach outlined in the Superfund guidance to address when it is appropriate to develop a Monte Carlo analysis. Depending on the nature of the contamination, the point estimate of risk, and the available data it may not be appropriate to conduct a Monte Carlo at all sites. The only site where a Monte Carlo was developed in the region, sofar, is the Hudson and essentially the results of the Monte Carlo supported those from the point estimate.

Please let me know if I can provide any additional information.

Marian
Robert Nunes

Robert Nunes

01/11/01 03:46 PM

To: Marian Olsen/R2/USEPA/US@EPA, Michael Sivak/R2/USEPA/US@EPA
cc:
Subject: Monte Carlo Guidance

Hi Marian and Mike - Gina suggested that I ask either of you for a copy of the current Monte Carlo guidance to see what is required for its preparation. Honeywell has provided a proposal for food web modelling for the Onondaga Lake site BERA which seems to be based on a Monte Carlo analysis that has yet to be prepared. Gina says EPA guidance indicates that a detailed workplan be prepared and reviewed before a Monte Carlo analysis be performed. Please let me know if you have something electronically or a hard copy that I could come down and pick up or photocopy. Thanks.

Bob
7-4254

Marian Olsen
01/16/01 07:05 AM

To: Robert Nunes/R2/USEPA/US@EPA
cc:
Subject: Re: Monte Carlo Guidance

Hi Bob,

The guidance is on the internet and available for anyone interested in reading it. I also have a copy of the external peer-review comments and can provide it is you are interested. The document, as indicated in your message, is Draft and has only recently completed external peer review. The external peer-reviewers raised a number of issues which are currently being addressed by the workgroup. We anticipate the final draft will be available in the Spring of this year. An important issue that will not change, is the need for a workplan. In another region, a Monte Carlo analysis was submitted, and they decided not to review it based on the lack of workplan.

Considering the amount of change that will be necessary, I would recommend using the 1997 guidance and recommendations as the basis for the decisions. I would also strongly recommend requiring the PRPs to submit a workplan so that all the issues regarding the parameter distributions, level of Monte Carlo Analysis, etc. can be resolved before they begin the development of the Monte Carlo Analysis. Also, please note, that we also require the development of a point estimate as the basis for comparison of the results of the Monte Carlo Analysis.

If you have any questions, please let me know.

Marian

Robert Nunes

Robert Nunes
01/12/01 12:35 PM

To: Marian Olsen/R2/USEPA/US@EPA
cc:
Subject: Re: Monte Carlo Guidance

Thank you. I do have one question. The guidance indicates that this is a "Draft - Do Not Cite or Quote". Is this draft available for discussion with DEC or distribution outside of the regulatory community?
Marian Olsen

Marian Olsen
01/11/01 04:01 PM

To: Robert Nunes/R2/USEPA/US@EPA
cc: Michael Sivak/R2/USEPA/US@EPA
Subject: Re: Monte Carlo Guidance

Hi Bob,

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